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U.S. PUBLIC HEALTH SERVICE. DIVISION OF
BIOLOGICAL STANDARDS.

BIOLOGICAL PRODUCTS. ADDITIONAL STANDARDS:
PACKED RED BLOOD CELLS (HUMAN).

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TITLE 42 - PUBLIC HEALTH,

CHAPTER 1--PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER F--QUARANTINE,
INSPECTION, LICENSING,

PART 73--BIOLOGICAL PRODUCTS,

ADDITIONAL STANDARDS: PACKED RED BLOOD CELLS (HUMAN).

On March 8, 1961, a notice of proposed rule making was published in the Federal Register proposing regulatory standards for the manufacture of Packed Red Blood Cells (Human).

Views and arguments respecting the proposed amendments were invited to be submitted within 60 days after publication of the notice in the Federal Register, and notice was given of intention to make any amendments that were adopted effective 60 days after the date of publication of the adopted amendments.

After consideration of all comments submitted, the following amendment to Part 73 of the Public Health Service regulations is hereby adopted to become effective 60 days after the date of publication in the Federal Register.

Amend Part 73 of the Public Health Service regulations by inserting at the end thereof the following center heading and sections:

ADDITIONAL STANDARDS: PACKED RED BLOOD
CELLS (HUMAN)

- Sec.
73.320 Proper name and definition.
73.321 Manufacture.
73.322 Pilot samples.
73.323 Containers.
73.324 Labeling.
73.325 Expiration date.
73.326 Storage.
73.327 General requirements.

Authority: §§73.320 to 73.327 issued under sec. 215, 58 Stat. 690 as amended; 42 U.S.C. 216. Interpret or apply sec. 351, 58 Stat. 702; 42 U.S.C. 262.

ADDITIONAL STANDARDS: PACKED RED BLOOD
CELLS (HUMAN)

§73.320 Proper name and definition.

The proper name of this product shall be Packed Red Blood Cells (Human). The product is defined as red blood cells remaining after separating plasma from sedimented Citrated Whole Blood (Human) to attain an hematocrit reading of from 60 percent to 70 percent.

§73.321 Manufacture.

Packed Red Blood Cells (Human) shall be prepared from Citrated Whole Blood (Human) that meets the standards prescribed in §§73.301 through 73.304. Packed Red Blood Cells (Human) may be prepared either by centrifugation conducted no later than six days after the date of blood collection or by normal undisturbed sedimentation before the expiration date of the blood. Packed Red Blood Cells (Human) shall be maintained at a temperature between 1° and 10° C. during processing, all of which shall be conducted so as to maintain the sterility of the product. Surfaces of apparatus, including needles and tubing, that come in contact with the product during its processing shall be clean, sterile and pyrogen-free. If the method of processing involves a vented system, the vent shall be one that will exclude microorganisms and maintain a sterile system.

§73.322 Pilot samples.

Pilot samples shall meet the following standards:

(a) One or more pilot samples shall be provided with each unit of Packed Red Blood Cells (Human) when issued or reissued except as provided in §73.304(e)(2).

(b) Pilot samples shall be either the original blood pilot sample or a sample of the Packed Red Blood Cells (Human) being processed.

(c) All containers of pilot samples accompanying a unit of Packed Red Blood Cells (Human) shall be filled at the time the blood is collected or at the time the final product is prepared, by the person performing the collection or preparation.

(d) All containers for all samples shall bear the donor's identification before they are filled.

(e) All containers for pilot samples accompanying a unit of cells shall be attached securely to the final container of Packed Red Blood Cells (Human) before the final container is filled, in a tamper-proof manner that will conspicuously indicate removal and reattachment.

§73.323 Containers.

Final containers used for Packed Red Blood Cells (Human) shall meet the requirements for blood containers prescribed in §73.304(c) and may be either the original blood containers or different containers.

§73.324 Labeling.

Except for the proper name, "Citrated Whole Blood (Human)", labels for Packed Red Blood Cells (Human) shall bear the information required for the Citrated Whole Blood (Human) from which it is processed.

§73.325 Expiration date.

The dating period for Packed Red Blood Cells (Human) shall be no longer than 21 days after the date of bleeding the donor for the Citrated Whole Blood (Human) from which it was processed, except that if the hermetic seal is broken during processing the dating period shall be no longer than 24 hours after the seal was broken.

§73.326 Storage.

Immediately after processing, the cells shall be placed in storage

and maintained within a 2° range between 1° and 6° C.

§73.327 General requirements.

Manufacturing responsibilities periodic check on sterile technique, shipment, reissue and recordkeeping shall be carried out in all respects for Packed Red Blood Cells (Human) as prescribed in §73.304 (a), (b), (d), (e), and (f) respectively for Whole Blood (Human).

Dated: August 2, 1961

[SEAL]

Luther L. Terry, M.D.
Surgeon General

Approved: August 8, 1961

Abraham Ribicoff
Secretary



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